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National Voluntary Laboratory Accreditation Program

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U.S. DEPARTMENT OF COMMERCE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY



# Bulk Asbestos Handbook

OPERATIONAL AND TECHNICAL REQUIREMENTS
OF THE
LABORATORY ACCREDITATION PROGRAM
FOR
BULK ASBESTOS ANALYSIS

October 1988

U.S. DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
Associate Director for Industry and Standards
Gaithersburg, Maryland 20899

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# NATIONAL INSTITUTE OF STANDARDS & TECHNOLOGY Research Information Center

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OPERATIONAL AND TECHNICAL REQUIREMENTS

OF THE

LABORATORY ACCREDITATION PROGRAM

FOR

**BULK ASBESTOS ANALYSIS** 

NISTIR 88-3879

National Voluntary Laboratory
Accreditation Program

Harvey W. Berger Lawrence S. Galowin Jeffrey Horlick

Center for Analytical Chemistry

Eric B. Steel Jennifer Verkouteren

U.S. DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Office of the Associate Director for
Industry and Standards
Gaithersburg, Maryland 20899



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#### I. PROGRAM SUMMARY

This document presents the operational and technical requirements to be fulfilled in order for laboratories to gain accreditation to perform bulk asbestos testing under NVLAP. All steps leading to accreditation are discussed. Technical requirements are explained and the way NVLAP criteria are applied is described.

Laboratory accreditation for bulk asbestos analysis was established by the National Institute of Standards and Technology <sup>1</sup> in response to the requirements set forth in Public Law 99-519, the Asbestos Hazard Emergency Response Act of 1986. The purpose of accreditation is to identify and recognize laboratories that produce reliable test data for the services covered.

Test Method Covered: 40 CFR Ch. I (1-1-87 edition) Pt 763, Subpt. F

App. A, pages 293-299 or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building materials.

Period of accreditation: One year

On-site assessment: Performed by NVLAP peer assessor, to determine

compliance with NVLAP criteria, after initial application and every two years thereafter.

Monitoring visits as required.

Assessors: Technical experts with experience in analysis of

bulk asbestos by polarized light microscopy.

Proficiency testing: Participation in proficiency testing is required.

Testing of pre-characterized quality assurance materials sent to the laboratory by NIST or an authorized contractor. Data to be returned to NIST for evaluation. Proficiency testing schedule

will be provided in advance.

Fees: Annual administrative/technical support fee,

on-site assessment fee, proficiency testing fees.

Granting Accreditation: Based upon successful on-site assessment,

proficiency testing, and technical evaluation of

applicable laboratory information.

<sup>1</sup> Formerly the National Bureau of Standards (NBS)

#### II. INTRODUCTION

#### Background

The U.S. Department of Commerce, National Institute of Standards and Technology (NIST)<sup>1</sup> administers the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP's function is to accredit public and private testing laboratories based on evaluation of their technical qualifications and competence for conducting specific test methods in specified fields of testing. Accreditation is granted on the basis of conformance with criteria published in the Code of Federal Regulations as part of the NVLAP procedures (15 CFR Part 7). (See Appendix A.)

This document is intended for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for the NVLAP accreditation under this program. This document is generally included in the NVLAP Application Package along with General Application Forms, Test Method Selection Lists, and other materials needed to apply for or renew accreditation. It presents the administrative and operational procedures and technical requirements of the accreditation program and should be retained and be readily accessible to laboratory personnel.

#### NVLAP Accreditation

Accreditation is granted only after thorough evaluation of the applicant has demonstrated that all NVLAP criteria have been met. The accreditation is formalized through issuance of a Certificate of Accreditation, Scope of Accreditation and publicized by announcement in various government and private media.

NVLAP accreditation is available to commercial laboratories, manufacturers' in-house laboratories, university laboratories, Federal, State, and local government laboratories. Foreign-based laboratories may be accredited by NIST if they meet the same requirements as domestic laboratories and pay any additional fees required.

#### Why NVLAP Accreditation ?

A laboratory may wish to be accredited for one or more of the following reasons: legal requirements (such as regulations or codes), contract specifications, or the desire to be recognized as demonstrably competent to meet the needs of its clients.

For accreditation to be meaningful, it must be granted by a clearly credible organization. NVLAP provides an unbiased third party evaluation and recognition of performance as well as expert technical assistance to upgrade laboratory performance when so needed.

 $<sup>^{</sup>m 1}$  Formerly the National Bureau of Standards (NBS)

#### Testing Laboratory Defined

NVLAP defines "testing laboratory" as an organization that provides services to measure, examine, test, calibrate, or otherwise determine the characteristics or performance of materials, products or systems.

#### Accreditation Defined

NVLAP accreditation signifies recognition of a testing laboratory's competence to perform specific test methods in specified fields of testing. It means that the laboratory's quality system, staff, facilities and equipment, calibration procedures, test methods and procedures, records, and test reports have all been evaluated and found to meet NVLAP criteria. NVLAP accreditation does not mean a guarantee (certification) of laboratory performance or of product test data; it is solely a finding of laboratory competence.

For further information about NVLAP, or for assistance in understanding and meeting the NVLAP requirements and criteria, please write or call:

NVLAP
National Institute of Standards and Technology
ADMIN A527
Gaithersburg, MD 20899
Phone: (301) 975-4016

#### III. ADMINISTRATIVE AND OPERATIONAL REQUIREMENTS

Note:

Administrative and operational requirements presented here are generally applicable to all NVLAP programs. Technical and proficiency requirements are specifically applicable to this asbestos accreditation program.

#### LABORATORY CODE NUMBER (LAB CODE)

Each participating laboratory is assigned a four-digit laboratory code number. The code number is used by the NVLAP staff for identification, filing, record-keeping, and database management. Participants are requested to put their Lab Code number on all correspondence with NVLAP. The Lab Code number is cross-referenced with the laboratory name and location in the NVLAP Directory of Accredited Laboratories.

#### ACCREDITATION PERIOD

Accreditation is granted for a period specified in the Accreditation Application Package (usually one year). The accreditation period begins on one of four dates: January 1, April 1, July 1, or October 1. Each laboratory retains its assigned accreditation date as long as it remains in the program; its accreditation expires and is renewed on that date.

#### RENEWAL

Each participating laboratory will be sent a renewal Application Package, well in advance of the expiration date of its accreditation, to allow sufficient time to complete the renewal process. The renewal application contains the same forms used for initial application. The laboratory may use copies of pages of previously submitted applications but must indicate any changes that may have occurred in personnel, equipment, facilities, or the scope of accreditation desired.

The technical requirements and fees for renewal are generally the same as for initial accreditation. The application and fees must be received by NIST prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

#### PUBLICIZING ACCREDITATION STATUS

#### BY NVLAP

NVLAP publishes an annual Directory of Accredited Laboratories. The Directory contains the name and address, scope of accreditation, contact person, and the accreditation renewal date for each accredited laboratory. Supplements to the Directory are published quarterly to cover interim accreditation actions

including initial accreditations, renewals, suspensions, terminations, and revocations. The Directory is distributed nationally and internationally to manufacturers, suppliers, retailers, professional and trade associations, code groups, and government agencies.

#### BY LABORATORIES

Accredited laboratories are encouraged, within specified limits, to publicize their accredited status. The major restriction is that advertising must not imply product certification by NIST or the U.S. Government. Laboratories and their clients may not reference their accredited status in consumer media, in product advertising, or on product labels, containers or packaging.

A laboratory may cite its accredited status and use NVLAP logos on reports, stationery, and in business and trade publications provided that it is clearly indicated that it is the laboratory which is accredited. NVLAP Lab Bulletin No. 3A provides more detailed guidance on how a laboratory may publicize its accredited status and the statements which may be made. (See Appendix.)

#### COMPLIANCE WITH EXISTING LAWS

Accreditation does not relieve the laboratory of the need to observe and comply with existing Federal, State, and local statutes, ordinances, or regulations that may be applicable to its operations, including consumer protection and antitrust laws.

#### ACCREDITATION PROCESS

Accreditation is granted following successful completion of a process which includes submission of an application and payment of fees by the laboratory, an on-site assessment, resolution of deficiencies identified during the on-site assessment, participation in proficiency testing, technical evaluation, and administrative review. The process is described in the following sections.

#### APPLICATION AND FEES

An Application Package is sent to a laboratory on request. It includes: General Application Forms, a Fee Calculation Sheet, and this document. The General Application Form must be completed and signed by an authorized representative of the laboratory. The authorized representative is one who can act on behalf of the laboratory and commit it to fulfill the NVLAP requirements. Before completing and signing the application, the authorized representative should review all documents and become totally familiar with NVLAP requirements. Although other laboratory staff may be designated to perform activities, such as handling proficiency testing or receiving an assessor, the authorized representative is the only one who can authorize a change in the scope or nature of the application.

In general, the accreditation fee is composed of several parts, some of which are fixed while others depend on the scope of accreditation desired and the specifics of the program. The total accreditation fee must be paid before accreditation can be granted. The individual parts of the accreditation fee include, as appropriate: an Administrative and Technical Support fee, a Test Method fee, a Proficiency Testing fee (excluding the cost of reference materials), and an On-Site Assessment fee. The fees for this accreditation program are shown in the Fee Calculation Sheet included in the Program Application Package.

The laboratory will be contacted to schedule a mutually acceptable date for the on-site assessment <u>after payment</u> of all required fees. It will also be notified if any additional information must be supplied, and if any applicable proficiency testing requirements must be completed, for the technical evaluation.

#### APPROVED SIGNATORY

Under NVLAP criteria, an accredited laboratory must have one or more individuals or personnel (approved signatories) in positions designated as having responsibility for signing <u>all test reports endorsed with the NVLAP logo</u>. This is the person(s) to be contacted by NVLAP, laboratory clients, or others if there are questions or problems with the report.

There is no formal requirement for nomination or approval of persons or laboratory positions designated as approved signatories. The laboratory should inform NVLAP of its appointments by completing the appropriate sections in the application for accreditation. Approved signatories should be persons or positions with adequate responsibility or authority within the organization, with adequate and appropriate technical capabilities, and without conflict of interest. The approved signatory may be the authorized representative who is responsible for signing the NVLAP Application Form.

Laboratory test reports carrying the NVLAP logo need not be signed individually by the approved signatory. Test report forms may be preprinted with the required information. Forms that are electronically or computer generated may have the information printed along with the test results.

#### TECHNICAL EXPERTS

NVLAP uses Technical Experts (TEs) as assessors and evaluators. They are engineers and scientists currently active in their field, consultants, college professors or retired persons. They are selected on the basis of their professional and academic achievements, experience in the field of testing, management and quality assurance experience, and tact in dealing with people. Their services are generally contracted as required; they are not NVLAP staff members.

<u>Assessors</u> are TEs selected to conduct an on-site assessment of a particular laboratory on the basis of how well their individual experience matches the type of testing to be assessed, as well as absence of conflicts of interest. The

laboratory has the right to appeal the assignment of an assessor and may request an alternate.

<u>Evaluators</u> are TEs selected to review the record of the laboratory as a whole, including the application, assessment report, deficiencies, corrections to deficiencies, and proficiency test results and, based on this record, to recommend whether or not a laboratory should be accredited. The evaluators are matched to the type of testing being evaluated and are selected to avoid conflicts of interest.

#### ON-SITE ASSESSMENT

Before initial accreditation and periodically thereafter, an on-site assessment of each laboratory is conducted to determine its compliance with the NVLAP criteria. The assessment is conducted by one or more NVLAP assessors selected on the basis of their expertise in the field of testing to be reviewed. Assessors use checklists developed by NVLAP so that each laboratory receives an assessment comparable to that received by others. However, assessors have considerable latitude to make judgments about a laboratory's compliance with the NVLAP criteria, depending on the assessor's experience and the unique circumstances of the laboratory. The laboratory may request a change of assigned assessor based on conflict-of-interest or prior business or professional associations.

Each laboratory will be contacted to arrange a mutually agreeable date for an assessment. The time needed to conduct an assessment varies, but one day is the norm. Every effort is made to conduct an assessment with as little disruption as possible to the normal operations of the laboratory. During the assessment the assessor will carry out the following functions:

- meet with management and supervisory personnel responsible for the laboratory's activities (for which accreditation is being sought) to review the assessment process with the individuals involved and to set the assessment agenda.
- examine the quality assurance system employed by the laboratory. The assessor may select and trace the history of one or more samples from receipt to final issuance of test reports. The assessor will conduct a thorough review of the laboratory's quality manual or equivalent, evaluate the training program, examine notebooks or records pertaining to the samples, check sample identification and tracking procedures, determine whether the appropriate environmental conditions are maintained, and examine copies of completed test reports.
- review records of periodic internal audits, use of check samples or participation in round robin testing or other similar programs.

The NVLAP General Operations Checklist and the Specific Operations Checklist for the Bulk Asbestos Program are included as appendices to this Handbook.

- review personnel records including resumes and job descriptions of key personnel, competency evaluations for all staff members who routinely perform the testing for which accreditation is sought, calibration or verification records for apparatus used, test reports, and sample control records.
- observe demonstrations of testing techniques and discuss them with the technical personnel to assure their understanding of the procedures.
- examine major equipment, apparatus, and facilities associated with testing for which the laboratory is seeking accreditation.

At the conclusion of the assessment, the assessor will conduct an exit briefing to discuss his or her observations with responsible laboratory staff and call attention to any deficiencies uncovered. A written summary of any deficiencies discussed will be left at the laboratory. The assessor will forward the assessment forms and a written summary to NIST.

If deficiencies have been noted, the laboratory must provide NVLAP with documentation or certification by the authorized representative, that the specified deficiencies have been corrected or that specific actions are being taken to correct the deficiencies.

If any deficiencies are noted at laboratories which are currently accredited, such deficiencies must be corrected within 30 days after notification or the laboratory may face possible revocation, suspension, or expiration of its accreditation. Any test equipment that is identified as out of calibration, should not be used until corrective action has been completed. All deficiencies noted for corrective action will be subject to thorough review and verification during subsequent assessments and technical evaluations.

#### MONITORING VISITS

In addition to regularly scheduled assessments, monitoring visits may be conducted by assessors or by NIST staff at any time during the accreditation period. Monitoring visits may occur for cause or on a random selection basis.

These visits serve to verify reported changes in the laboratory's personnel, facilities, and operations or to explore possible reasons for poor performance in proficiency testing.

The scope of a monitoring visit may range from checking a few designated items to a complete review. Failure to cooperate with NVLAP assessors will be grounds for initiation of adverse accreditation action.

#### PROFICIENCY TESTING

Proficiency testing is an integral part of the NVLAP accreditation process. Demonstration of appropriate facilities, equipment, personnel, etc., is

essential, but may not be sufficient for the evaluation of laboratory competence. The actual determination of test data using special proficiency testing samples provides NVLAP with a means for determining the overall effectiveness of the laboratory.

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of inter-laboratory comparisons. Each accreditation program has unique proficiency testing requirements. The data are analyzed by NVLAP and summary reports of the results are sent to the participants.

For many test methods, proficiency testing results are good indicators of a laboratory's testing capability. Information obtained from proficiency testing helps to identify problems in a laboratory. If problems are found, NVLAP staff members work with the laboratory staff to solve them. If problems with the test method are suspected, NVLAP provides information to the appropriate standards writing bodies.

The specific proficiency testing requirements for this Program are included in Section V of this document.

#### TECHNICAL EVALUATION

After a laboratory has completed all the technical requirements of a Program and is ready for an accreditation action, a final technical evaluation is conducted by experts chosen for their experience and knowledge of the pertinent test methods. They review records on an applicant laboratory and base their evaluation on:

- information provided on the application;
- on-site assessment reports;
- actions taken by the laboratory to correct deficiencies;
- results of proficiency testing; and
- information from any monitoring visits of the laboratory.

If the technical evaluation reveals additional deficiencies, written notification describing them will be made to the laboratory. The laboratory must respond within 30 days of such notification and provide documentation or certification by the authorized representative that the specified deficiencies have been corrected. Clarification of some issues may be requested by telephone. All deficiencies must be corrected before accreditation can be granted or renewed.

#### ADMINISTRATIVE REVIEW

After the technical evaluation has been completed, the NVLAP staff prepares an administrative recommendation whether the laboratory should be granted or denied accreditation. This recommendation is based on a review of the technical evaluation and other records to ensure that all NVLAP technical, financial and administrative obligations have been satisfied.

#### ACCREDITATION ACTIONS

Based on the technical findings pertaining to the laboratory's compliance with the NVLAP criteria, the Associate Director for Industry and Standards (ADIS), acting for the Director of NIST, makes one of the following decisions:

Accreditation The recommendation forms the basis for granting accreditation and a Certificate of Accreditation is issued to the laboratory.

<u>Denial</u> The laboratory is notified of the intent to deny accreditation and the reason(s) therefor.

Suspension If a laboratory is found to have violated the terms of its accreditation, the laboratory will be notified of the reasons for and conditions of the suspension and the action(s) that the laboratory must take to have accreditation reinstated.

If a laboratory is found to have violated the terms of its accreditation, the laboratory is notified of the intent to revoke accreditation and the reasons therefor. The laboratory may be given the option of voluntarily terminating accreditation. If accreditation is revoked, the laboratory must return its Certificate of Accreditation and must cease using the NVLAP logo on any of its reports, correspondence, or advertising.

If denial or revocation has been proposed, the laboratory may request a hearing, under United States Code 5 U.S.C. 556, within 30 days of the date of receipt of the notification. If a hearing is not requested, the action becomes final upon the expiration of that 30-day period.

After a participant's accreditation has been terminated, whether voluntarily or through adverse action, the accreditation certificate must be returned to NVLAP. If a laboratory elects not to renew or voluntarily chooses to terminate its accreditation at any time, the notification of such intention should be forwarded to NIST in writing.

#### IV. TECHNICAL REQUIREMENTS

The <u>Criteria for Accreditation</u>, Section 7.33 of the NVLAP Procedures (see Appendix A), provides the basis for the technical evaluation of a laboratory. This section provides interpretive comments and additional information to adapt the criteria for specific application to the Bulk Asbestos Laboratory Accreditation Program. Except where specifically noted otherwise, these comments <u>do not</u> supersede the <u>Criteria for Accreditation</u>.

#### Scope of the Program

The NVLAP Bulk Asbestos Program offers accreditation for the following test method:

40 CFR Ch. I (1-1-87 edition) Pt 763, Subpt. F App. A, pages 293-299 or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building materials.

#### Comments on QUALITY SYSTEM (see Procedures Sec. 7.33a)

The Quality System requirements are designed to promote laboratory practices that ensure technical integrity of the analyses and adherence to quality assurance standards. The laboratory must maintain a Quality Manual which documents the laboratory's practices and the specific steps taken to ensure quality testing. The Quality Manual must contain or refer to documentation that describes and details the laboratory's implementation of procedures covering all technical requirements in this section. For the analysis of asbestos, these procedures include: sample custody, contamination, instrument calibration, staff qualifications, and laboratory characterization. This information will be reviewed by NVLAP assessors during on-site assessments.

The Quality Manual must contain procedures for log-in of sample materials, description of materials, and criteria for acceptance or rejection of materials for test.

Contamination is a critical factor in the analysis of asbestos. The Quality Manual must describe the laboratory's system for maintaining a contamination-free work space. It must include the frequency and timing of checks for contamination of laboratory equipment or supplies which are used in the analysis of asbestos. These include, but are not restricted to, glass slides, coverslips, refractive index liquids, sampling instruments, analytical instruments (microscopes), work stations, and cleaning fluids. The Manual must also describe procedures for dealing with contamination.

The Quality System must provide for routine checks of the competence of analysts and others involved in the analysis of asbestos. The laboratory's Quality Assurance (QA) analyses must represent at least 10% of the total number of analyses performed.

The Quality Manual must describe how the laboratory assures the accuracy and consistency of its analyses. The laboratory is responsible for scheduling the timing and frequency of testing with standard samples and duplicate analyses so that errors in testing can be detected and corrected.

Records must be kept of all quality assurance activities. Test data from quality assurance checks performed in the laboratory (or with other laboratories) must be summarized and retained for use by the laboratory in monitoring its performance.

The following documents should be available in the laboratory as reference in developing and maintaining the Quality System:

- General reference text on optical mineralogy or crystallography.
- 40 CFR Part 763, Vol. 52, No. 210 "Asbestos-Containing Materials in Schools; Final Rule and Notice".
- A draft American Society for Testing and Materials method for polarized light microscope analysis of asbestos in building materials is currently under review by ASTM and may be used as an analytical aid by the laboratory. It is recommended that the laboratory acquire the draft method by contacting Ms. Sharon Kauffman, the ASTM D22 Committee Administrative Officer, at 1916 Race Street, Philadelphia, PA 19103 (215)-299-5400.

#### Comments on STAFF (See Procedures Sec. 7.33b)

The laboratory must maintain a list of position descriptions and staff assigned to those positions. The laboratory must ensure that analysts and supervisors are adequately qualified to conduct polarized light microscopy and its application to crystalline materials, including the measurement of the index of refraction by the immersion method through Becke line technique. Other techniques, such as dispersion staining and oblique illumination, may be helpful.

The laboratory must have a designated quality assurance supervisor to define and maintain the Quality System and the associated Quality Manual.

The laboratory must maintain a personnel folder for each staff member, including: a resume of qualifications, training, laboratory procedures to which assigned, and the results of periodic testing performance (quality assurance testing) reviews. Performance reviews of staff members will include intra-operator tests, inter-operator tests and between-laboratory tests. The laboratory shall have a description of its training program for ensuring that staff are able to perform tests properly and uniformly.

# Comments on FACILITIES AND EQUIPMENT (See Procedures Sec. 7.33c)

The laboratory must have proper facilities for storage of bulk asbestos to prevent contamination and maintain sample identification. Safe working conditions while handling bulk asbestos must be maintained.

The list of required and optional equipment follows. All required items must be regularly checked to ensure that they are in working order.

- NIST traceable standards for the major asbestos types
- biohazard hood of class I or better (see Note below)
- sampling utensils (razor knives, forceps, probe needles, etc.)
- microscope slides and cover slips
- refractive index liquids: 1.490-1.570, 1.590-1.720 in increments of less than or equal to 0.005; high dispersion liquids are optional
- magnifying glass or low power binocular microscope, approximately 10-45X, with light source
- mortar and pestle

#### Polarized light microscope:

- binocular or monocular with crosshair reticle, or functional equivalent, and a magnification of at least 8X
- 10X, 20X, and 45X objectives, or similar magnifications
- light source (with optional blue "day light" filter)
- 360 degree rotatable stage
- substage condenser with iris diaphragm
- polarizer and analyzer which can be placed at 90 degrees to one another
- accessory slot for wave plates and compensators
- wave retardation plate: approximately 550 nanometer
- dispersion staining objective complete with accessories or a demonstrated equivalent (optional)

#### <u>Comments on SUB-FACILITIES</u> (See Procedures Sec. 7.33c)

Main (laboratory) facilities and sub-facilities are defined in NVLAP POLICY GUIDE 10, which is included in this Handbook as APPENDIX D. To qualify as a sub-facility, a laboratory <u>must be technically dependent</u> on the main facility; technical management and supervision must be provided by the main facility. Quality assurance activities of the sub-facility must be directed by the main facility. The nature, scope, and frequency of on-site quality assurance reviews by the main facility Quality Assurance Manager, must be clearly defined in the Quality Assurance manual and appropriate for the nature and scope of work performed by the sub-facility. Copies of all permanent quality assurance and personnel records must be retained at the main facility. Quality assurance

Note: A Class I Biohazard Hood, or better, is suggested for the safe and non-contaminating handling of bulk asbestos materials in the laboratory. For the accreditation program, the purpose of the hood is to protect the laboratory environment from contamination with the potentially large quantities of asbestos handled during routine preparation and macroscopic examination of building materials. Environmental and safety issues including all requirements by Federal, State, and local agencies are the responsibility of the laboratory. A Class I hood is a ventilated cabinet for personnel and environmental protection, with an inward airflow away from the operator. The cabinet exhaust air may be treated to protect the environment before it is discharged to the outside atmosphere or may exhaust HEPA filtered air back into the laboratory. A minimum inward velocity of air into the hood opening of 75 fpm is recommended.

Reference: Standard Number 49, National Sanitation Foundation, Ann Arbor, MI, (313)-769-8010.

data from each sub-facility must be regularly compared both to the main facility's data and data from other sub-facilities. Records of such comparisons must be retained in quality assurance records along with actions taken to evaluate and resolve differences.

#### Comments on CALIBRATION (See Procedures Sec. 7.33d)

The Quality Manual must specify the frequency and timing of calibration of all equipment, including the polarized light microscope(s), and the verification of refractive index liquids used. Records must be kept detailing calibration and maintenance.

#### Comments on TEST METHODS AND PROCEDURES (See Procedures Sec. 7.33e)

The laboratory shall use 40 CFR Ch. I (1-1-87 edition) Pt 763, Subpt. F App. A, pages 293-299 or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building materials. The laboratory Director is responsible for ensuring that current revisions of the method are implemented by the laboratory.

The work space must be monitored for asbestos contamination on a routine basis. Laboratory blanks, using asbestos-free materials should, be prepared and analyzed with sufficient frequency to detect contamination.

The laboratory must have written procedures covering all aspects of handling, analyzing, storing, and disposing of samples and materials. These procedures must be readily accessible to all personnel concerned.

To document the positive identification of asbestos in a sample, the analyst(s) must record the following optical properties: morphology, color and pleochroism, index of refraction parallel and perpendicular to elongation, birefringence, extinction characteristics and sign of elongation, and any other distinguishing characteristics observed. This information must be present in the record book used to record sample analysis. The analyst must sign or initial and date each analysis recorded in the laboratory note book.

#### Comments on RECORDS (See Procedures Sec. 7.33f)

The laboratory must maintain a record-keeping system as described in its Quality Assurance Manual. Records may be kept in hard copy or computer form, but they must be readily accessible. Adequate security must be maintained to assure survival and retrievability of records and test reports for a minimum of three years. This requirement supersedes the criterion in Appendix A Section 7-33(g)(3). Records to be maintained include those addressing:

- sample custody
- original data collected by the analyst
- contamination monitoring data
- calibration and verification
- personnel
- quality assurance
- equipment and maintenance
- test reports

#### Comments on TEST REPORTS (See Procedures Sec. 7.33g)

The following information should be reported for each sample: color, presence or absence of asbestos, type or types of asbestos present, estimate of the area percentage of each type of asbestos present, estimate of area percentage of other fibrous materials present, and identity of other fibrous materials and matrix materials, if known. If the sample submitted for analysis is inhomogeneous and subsamples of the components were analyzed separately, this should be stated, but the separate components should be combined in proportion to their abundances and a single analysis provided for the sample.

#### V. PROFICIENCY TESTING

Proficiency testing is an integral requirement of the NVLAP evaluation process. The proficiency testing program may be conducted by NIST or by an NIST approved contract laboratory. The proficiency testing materials are expected to be challenging, but representative, examples of bulk insulation materials or their derivatives. The material will test the laboratory's ability to follow the method and achieve the proper accuracy, precision, and detection limits. Participation in proficiency testing is required for initial accreditation and continued accreditation.

Each laboratory will be sent test samples, data sheets, and an information package containing specific instructions for performing the test and reporting the results. The test must be conducted in accordance with the specified test method using the laboratory's normal operating procedures. Any special NVLAP instructions must also be followed. The special instructions are designed to ensure uniformity in procedures among participants. Completed data sheets must be returned to NIST for analysis by the date specified on the data sheets.

The work must not be contracted out to another laboratory.

Proficiency testing may involve materials or artifacts that must be returned to NIST for use by other participants. These materials must be protected from harm and damage both in the laboratory and during shipment back to NIST. Examples of such materials and artifacts are: permanently mounted slides, photographs, glasses, and special optical materials. These materials may be used to determine testing performance for specific sub-parts of the test method. Unless otherwise noted, laboratories should keep proficiency testing materials for use as in-house instructional materials.

All analysts (including those in sub-facilities) must participate in proficiency testing. Each analyst must separately analyze, record, and report test results. A single result is to be reported back to NVLAP by the laboratory. The test results are to be used for inter-analyst comparisons and entered into the quality system records.

The results of the proficiency testing program will be reported to the participants and in appropriate documents and reports. The identity and performance of individual laboratories will remain confidential. The results of proficiency testing will be made available to on-site assessors for use

during laboratory visits. Any problems indicated by proficiency testing, will be discussed with appropriate laboratory personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based on satisfactory resolution of proficiency testing deficiencies.

#### VI. ON-SITE ASSESSMENT

Before accreditation can be granted, the laboratory must undergo a successful on-site assessment, or resolve any departures from the NVLAP criteria noted during an assessment.

A NVLAP assessor will arrange with the laboratory in advance for the on-site assessment. The laboratory should be in good order and prepared to demonstrate testing. The assessor will try to minimize disruption to the normal working routine. All observations are held in strictest confidence.

The assessor will use NVLAP checklists containing specific questions about all aspects of the visit. The checklists, based on NVLAP criteria for accreditation, serve to ensure a complete assessment and that all assessors cover the same items at each laboratory.

The laboratory will be responsible for demonstrating its competence to analyze asbestos samples following the practice outlined in its Quality Manual. Staff members involved in the analysis of samples will be asked to demonstrate their competence, as required, during an on-site visit. In particular, analysts should be able to demonstrate their ability to measure refractive index and other optical properties and to identify the various types of asbestos.

The assessor will also have prepared samples for analysis by laboratory personnel during the assessment. Observation of the measurement process will afford the assessor an immediate opportunity to evaluate procedures and techniques and will provide an opportunity to laboratory personnel to gain insights and advice from a technical peer. This activity is not part of the proficiency testing program but will indicate to both the assessor and laboratory any problems that might arise in proficiency testing.

Both central laboratories and mobile or satellite laboratories must be included in the assessment if those facilities are to be included in the accreditation. An assessment of a main central laboratory will normally take one day. Assessments of sub-facilities may require one or more additional days depending on their number and location.

The agenda for a typical on-site visit is given below.

- 1. Assessor conducts an entry briefing with laboratory manager to explain the purpose of the on-site visit and to discuss the schedule for the day. At the discretion of the laboratory manager, other staff may attend the briefing.
- 2. Assessor reviews equipment calibration and maintenance records, record

keeping procedures, Quality System manual(s), laboratory test reports, and personnel competency records. Although a staff member is available to answer questions, the assessor may wish to review the documents alone. The assessor does not usually ask to take any laboratory documents with him.

- 3. Assessor observes the demonstration of selected procedures and interviews the personnel. The demonstrations should include specimen preparation and the use of all major equipment.
- 4. Assessor physically examines equipment and facilities.
- 5. Assessor examines mobile or satellite facilities. Laboratory personnel should be available to provide transportation and to accompany the assessor. If the laboratory maintains more than one similar mobile or satellite laboratory, the number to be visited will be based on the number and location of the facilities. The central laboratory must demonstrate that all sites are operated and equipped in the same manner as described in the Quality Manual.
- 6. The assessor needs time during the day to complete NVLAP paperwork.
- 7. An exit briefing is held with the laboratory manager and staff to discuss the assessor's findings. Deficiencies are discussed and resolutions are mapped out. Items that must be addressed before accreditation can be granted are emphasized. Items that have been corrected during the on-site and any recommendations are specially noted.
- 8. The assessor completes the Assessment Report, to be signed by the laboratory representative. A copy of this report is left at the laboratory.



#### APPENDICES

- A. NVLAP Procedures, Subpart D,
  Conditions and Criteria for Accreditation
- B. NVLAP Lab Bulletin No. 3A
- C. NVLAP Lab Bulletin No. 19
- D. NVLAP Policy Guide 10
- E. NVLAP General Operations Checklist
- F. Specific Operations Checklist (Bulk Asbestos Program)



#### SUBPART D - CONDITIONS AND CRITERIA FOR ACCREDITATION

# Sec. 7.31 Application of accreditation conditions and criteria.

- (a) To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in Section 7.32 and the criteria set out in Section 7.33 as tailored for specific LAPs.
- (b) The conditions leading to accreditation include acceptance of the responsibilities of an accredited laboratory and requirements for information disclosure.
- (c) The criteria are tailored and interpreted for the test methods, types of test methods, products, services or standards of the relevant LAP. These tailored criteria are the technical requirements for accreditation developed through the procedures of Section 7.15.
- (d) In applying the conditions, criteria, and technical requirements for accreditation, the Director of OPSP shall not:
  - (1) Prohibit accreditation solely on the basis of a laboratory's affiliation or nonaffiliation with manufacturing, distributing, or vending organizations, or because the laboratory is a foreign firm; or
  - (2) Develop, modify, or promulgate test methods, standards, or comparable administrative rules.

# Sec. 7.32 Conditions for accreditation.

- (a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:
  - (1) Be assessed and evaluated initially and on a periodic basis;
  - (2) Demonstrate, on request, that it is able to perform the tests representative of those for which it is seeking accreditation;
  - (3) Pay all relevant fees;
  - (4) Participate in proficiency testing as required.
  - (5) Be capable of performing the tests for which it is accredited according to the latest version of the test method within one year after its publication or within another time limit specified by the Director of OPSP:
  - (6) Limit the representation of the scope of its accreditation to only those tests or services for which accreditation is granted;
  - (7) Limit all its test work or services for clients to those areas where competence and capacity are available;
  - (8) Limit advertising of its accredited status to letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications, and use the NVLAP logo under guidance provided by the Director of OPSP;
  - (9) Inform its clients that the laboratory's accreditation or any of its test reports in no way constitutes or implies product certification, approval, or endorsement by NBS;
  - (10) Maintain records of all actions taken in response to testing complaints for a minimum of one year;

(11) Maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render test reports objectively and without bias is not adversely affected;

(12) Report to the Director of OPSP within 30 days any major changes involving the location, ownership, management structure, authorized representative, approved signatories, or facilities of the laboratory:

and

(13) Return to the Director of OPSP the certificate of accreditation for possible revision or other action should it:

(i) be requested to do so by the Director of OPSP;

- (ii) voluntarily terminate its accredited status; or(iii) become unable to conform to any of these conditions or the applicable criteria of Section 7.33 and related technical requirements.
- (b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information:

Legal name and full address;

(2) Ownership of the laboratory;

(3) Organization chart defining relationships that are relevant to performing testing covered in the accreditation request;

(4) General description of the laboratory, including its facilities and

scope of operation;

(5) Name and telephone number of the authorized representative of the laboratory;

(6) Names or titles and qualifications of laboratory staff nominated to serve as approved signatories of test reports that reference NVLAP accreditation; and

(7) Other information as may be needed for the specific LAP(s) in which

accreditation is sought.

# Sec. 7.33 Criteria for accreditation.

(a) Quality System. (1) The laboratory shall operate under an internal quality assurance program appropriate to the type, range, and volume of work performed. The quality assurance program must be designed to ensure the required degree of accuracy and precision of the laboratory's work and should include key elements of document control, sample control, data validation, and corrective action. The quality assurance program must be documented in a quality manual or equivalent (e.g., operations notebook) which is available for use by laboratory staff. A person(s) must be identified as having responsibility for maintaining the quality manual.

(2) The quality manual must include as appropriate:

(i) The laboratory's quality assurance policies including procedures for corrective action for detected test discrepancies;

(ii) Quality assurance responsibilities for each function of the laboratory; (iii) Specific quality assurance practices and procedures for each test, type

of test, or other specifically delineated function performed;

(iv) Specific procedures for retesting, control charts, reference materials, and interlaboratory tests; and

(v) Procedures for dealing with testing complaints.

(3) The laboratory shall periodically review its quality assurance system by or on behalf of management to ensure it's continued effectiveness. These reviews must be recorded with details of any corrective action taken.

(b) Staff. (1) The laboratory shall:

(i) Be staffed by individuals having the necessary education, training, technical knowledge, and experience for their assigned functions; and

(ii) Have a job description for each professional, scientific, supervisory and technical position, including the necessary education, training, technical knowledge, and experience.

(2) The laboratory shall document the test methods each staff member has been

assigned to perform.

(3) The laboratory shall have a description of its training program for ensuring that new or untrained staff are able to perform tests properly and uniformly to the requisite degree of precision and accuracy.

(4) The laboratory shall be organized:

(i) So that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work; and

(ii) In such a way that staff members are aware of both the extent and the limitation of their area of responsibility.

(5) The laboratory shall have a technical manager (or similar title) who has overall responsibility for the technical operations of the laboratory.

(6) The laboratory shall have one or more signatories approved by the Director of OPSP to sign test reports that reference NVLAP accreditation. Approved signatories shall:

(i) Be competent to make a critical evaluation of test results; and

(ii) Occupy positions within the laboratory's organization which makes them responsible for the adequacy of test results.

(c) <u>Facilities and Equipment</u>. (1) The laboratory shall be furnished with all items of equipment and facilities for the correct performance of the tests and measurements for which accreditation is granted and shall have adequate space, lighting, and environmental control, and monitoring to ensure

compliance with prescribed testing conditions.

(2) All equipment must be properly maintained to ensure protection from corrosion and other causes of deterioration. Instructions for a proper maintenance procedure for those items of equipment which require periodic maintenance must be available. Any item of equipment or component thereof which has been subjected to overloading or mishandling, gives suspect results, or has been shown by calibration or otherwise to be defective, must be taken out of service and clearly labelled until it has been repaired. When placed back in service, this equipment must be shown by test or calibration to be performing its function satisfactorily.

(3) Records of each major item of equipment must be maintained. Each record

must include:

(i) The name of the item of equipment:

(ii) The manufacturer's name and type, identification and serial number;

(iii) Date received and date placed in service;

(iv) Current location, where appropriate;

(v) Details of maintenance; and

(vi) Date of last calibration, next calibration due date, and calibration report references.

(d) Calibration. The laboratory shall:

(1) Calibrate new testing equipment before putting it into service:

(2) Recalibrate, at regular intervals, in-service testing equipment with the calibration status readily available to the operator;

(3) Perform checks of in-service testing equipment between the regular

calibration intervals, where relevant;

(4) Maintain adequate records of all calibrations and recalibrations; and

(5) Provide traceability of all calibrations and reference standards of measurement where these standards exist. Where traceability of measurements to primary (national or international) standards is not applicable, the laboratory shall provide satisfactory evidence of the accuracy or reliability of test results (e.g., by participation in a suitable program of interlaboratory comparison).

(e) Test Methods and Procedures. The laboratory shall:

(1) Conform in all respects with the test methods and procedures required by the specifications against which the test item is to be tested, except that whenever a departure becomes necessary for technical reasons the departure must be acceptable to the client and recorded in the test report;

(2) Have data to prove that any departures from standard methods and/or procedures due to apparatus design or for other reasons do not detràct

from the expected or required precision of the measurement;

(3) Maintain a test plan for implementing testing standards and procedures including adequate instructions on the use and operation of all relevant equipment, on the handling and preparation of test items (where applicable), and on standard testing techniques where the absence of such instructions could compromise the test. All instructions, testing standards, specifications, manuals, and reference data relevant to the work of the laboratory must be kept up-to-date and made readily available to the staff;

(4) Maintain measures for the detection and resolution of in-process testing discrepancies for manual and automatic test equipment and

electronic data processing equipment, where applicable;

(5) Maintain a system for identifying samples or items to be tested, which remains in force from the date of receipt of the item to the date of its disposal, either through documents or through marking to ensure that there is no confusion regarding the identity of the samples or test items and the results of the measurements made; and

(6) Maintain rules for the receipt, retention, and disposal of test items, including procedures for storage and handling precautions to prevent damage to test items which could invalidate the test results. Any relevant instructions provided with the tested item must be observed.

(f) Records. The laboratory shall:

(1) Maintain a record system which contains sufficient information to

permit verification of any issued report;

(2) Retain all original observations, calculations and derived data, and calibration records for one year unless a longer period is specified; and

(3) Hold records secure and in confidence, as required.

(q) Test Reports. (1) The laboratory shall issue test reports of its work which accurately, clearly, and unambiguously present the specified test results and all required information. Each test report must include the following information as applicable:

(i) Name and address of the laboratory:

(ii) Identification of the test report by serial number, date, or other appropriate means;

(iii) Name and address of client:

- (iv) Description and identification of the test specimen, sample, or lot of material represented:
  - (v) Identification of the test specification, method, or procedure used:

(vi) Description of sampling procedure, if appropriate;

- (vii) Any deviations, additions to, or exclusions from the test specifications:
- (viii) Measurements, examinations, and derived results supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified:

(ix) A statement of measurement uncertainty where relevant;

- (x) Identification of the organization and the person accepting technical responsibility for the test report and date of issue;
- (xi) A statement that the report must not be reproduced except in full with the approval of the laboratory; and
- (xii) A statement to the effect that the test report relates only to the items tested.
- (2) The laboratory shall issue corrections or additions to a test report only by a further document suitably marked, e.g. "Supplement to test report serial number ...., which meets the relevant requirements of Section 7.33(q)(1).

(3) The laboratory shall retain a copy of each test report issued for one year unless a longer period is specified by the Director of OPSP.

(4) The laboratory shall ensure that all test reports endorsed with the NVLAP logo are signed by an approved signatory.



National Voluntary Laboratory Accreditation Program



U.S. Department of Commerce in cooperation with the National Bureau of Standards

# Bulletin

Lab Bulletin No. 3A

January 1, 1985

# INFORMING THE PUBLIC OF YOUR ACCREDITATION STATUS

# Summary

This Bulletin supersedes NVLAP Lab Bulletin No. 3 dated October 1, 1981. It reflects significant changes made to the NVLAP procedures (Title 15, Part 7, of the Code of Federal Regulations) which became effective on December 10, 1984.

The Bulletin is addressed primarily to personnel at accredited laboratories who are responsible for communicating the laboratory's accreditation status to clients and the public, through advertising, issuance of test reports, use of the NVLAP logo, etc.

The Bulletin's purpose is to "provide guidance on referencing the laboratory's accredited status, and use of the NVLAP logo by the laboratory and its clients," in accordance with provisions of the NVLAP Procedures.

#### Background

NVLAP was established to assist industry and government in identifying competent testing laboratories. NVLAP accreditation means that a laboratory is competent to perform specific test methods in selected fields of testing. The NVLAP Procedures are the bases upon which the entire program operates and accomplishes accreditation of laboratories. Parts A and B of the Procedures provide general information and the method by which a new Laboratory Accreditation Program (LAP), in a new field of testing, may be requested and established. Parts C and D of the Procedures, of more concern to accredited laboratories, describe how a laboratory becomes accredited and the conditions and criteria for initial and continued accreditation. This Bulletin is concerned principally with issues in Part D of the Procedures.

# Requirements and Guidance

To become accredited and maintain accreditation a laboratory shall:

limit the representation of the scope of its accreditation to only those tests or services for which accreditation is granted

A laboratory accredited by NVLAP may use the following statement on its letterheads and in trade or other publications: "Accredited by the National Bureau of Standards, National Voluntary Laboratory Accreditation Program for selected test methods for --(identify product or service area(s))." This statement could, for example, be placed at the bottom of the laboratory letterhead.

A laboratory's letterhead containing a reference to its NVLAP accreditation may be used in any direct solicitation for business from potential customers. It is recommended that a copy of the NVLAP Certificate and Scope of Accreditation be appended to such a solicitation.

To become accredited and maintain accreditation a laboratory shall:

limit advertising of its accredited status to letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications, and use the NYLAP logo under guidance provided by NBS

A statement about NVLAP accreditation and the NVLAP logo may be used on reports and data sheets containing test data obtained by a laboratory provided the tests or services are performed in accordance with the terms of its accreditation. The NVLAP logo may not be used on test reports or data sheets during any period of suspended or expired accreditation or after voluntary or involuntary termination of accreditation.

The nature or type of product advertising prohibited by NVLAP procedures includes any advertising that is intended to encourage a consumer to purchase a product because it was tested by an accredited laboratory, whether that advertising appears in consumer media, the business media, or at a point of sale to consumers.

News stories and advertising by laboratories of their accredited status in the trade press is not only permissible but encouraged. The use of advertisements in the trade press is consistent with NVLAP procedures.

The "consumer media" to be avoided include popular periodicals such as Time, Good Housekeeping, etc., and newspapers such as the Washington Post or the New York Times. The term "consumer media" does not include business publications such as Barron's, or the Wall Street Journal which are oriented to the business community and in which products per se normally are not advertised.

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To become accredited and maintain accreditation a laboratory shall:

inform its clients that the laboratory's accreditation or any of its test reports in no way constitutes or implies product certification, approval, or endorsement by NBS

Laboratory accreditation by NBS confers recognition that a laboratory has been found competent to perform specific test methods or services in a selected field(s) of testing. Laboratories must avoid all inference that accreditation under NVLAP carries with it an endorsement, approval, or recommendation of the products tested by the laboratories.

To become accredited and maintain accreditation a laboratory shall:

assure that all test reports endorsed with the NVLAP logo are signed by an approved signatory

An approved signatory is an officer or employee of the laboratory, identified by name or position, who has been accepted by NVLAP as being responsible for the issuance of test reports under this condition of NVLAP accreditation. A laboratory seeking initial accreditation or reaccreditation must specify (a) one or more individuals, or (b) position(s) within the organization for which it requests acceptance as an approved signatory.

Computer or machine generated test reports that contain the NVLAP logo need not be signed but must have the printed name of the approved signatory.

# Questions About Accreditation

If you have questions about what is an acceptable method of advertising in areas not specifically covered in this Lab Bulletin or about the propriety or acceptability of a particular statement, advertising media, or use of information about your NVLAP accreditation status, please contact NVLAP before your publicity program is implemented.

Call 301-921-3431 or

Send your questions to:

Harvey W. Berger Associate Manager, Laboratory Accreditation National Bureau of Standards ADMIN A531 Gaithersburg, MD 20899



National Voluntary Laboratory Accreditation Program



U.S. Department of Commerce in cooperation with the National Bureau of Standards

# Bulletin

Policy Bulletin No. 19 August 1986

# SATISFACTORY PROFICIENCY TESTING IS A REQUIREMENT FOR ACCREDITATION

Accreditation by the National Bureau of Standards, under the National Voluntary Laboratory Accreditation Program (NVLAP), requires that a laboratory meet all performance requirements and criteria as determined by on-site assessments and proficiency testing.

If, as the result of on-site assessments, deficiencies are found, the laboratory must satisfactorily resolve those deficiencies, in order to obtain initial accreditation or maintain accreditation.

Unsatisfactory participation in any NVLAP proficiency testing program is a technical deficiency which must be resolved in order to obtain initial accreditation or maintain accreditation.

Unsatisfactory participation in NVLAP proficiency testing programs is defined as, but not limited to, one or more of the following:

- 1. Failure to meet specified proficiency testing performance requirements prescribed by a standard or test method for which the laboratory is seeking accreditation. (Example: ANSI Standard N13.11 for the Dosimetry LAP.)
- 2. Failure to participate in a regularly scheduled "round" of proficiency testing for which the laboratory has received instructions and/or materials.
- 3. Failure to submit laboratory control data as required. (Example: Within laboratory control data to be submitted twice annually for the Concrete LAP.)
- 4. Performance as a statistically outlying laboratory in two successive rounds of proficiency testing or showing a general pattern of outlying test results over three or more rounds.
- 5. Failure to produce test data within acceptable limits of error when testing NBS Standard Reference Materials or special artifacts whose properties are well characterized and known to NBS/NVLAP.

NVLAP will notify the laboratory of proficiency testing deficiency(s) and actions to be taken to resolve the deficiency(s). Denial or suspension of accreditation will result from failure to resolve deficiencies.

For further information contact: Harvey W. Berger, Manager or Jeffrey Horlick, Proficiency Testing Project Leader, (301) 921-3431.



June 1988 APPENDIX D

# NVLAP POLICY GUIDE 10

This Policy Bulletin presents NVLAP definitions of the types of laboratory facilities which may be granted NVLAP accreditation, the requirements and conditions that must be satisfied in order to achieve accreditation, and procedures that NVLAP will follow in evaluating various types of facilities for their conformance to accreditation criteria.

# Definitions:

# a. Main (laboratory) facility:

- (1) permanently (at all times) maintains staff, equipment, procedures, documentation, and facilities necessary to perform the tests, for which it seeks accreditation;
- (2) implements all quality assurance procedures;
- (3) maintains and retains all records, and issues test reports; and
- (4) may be a permanently fixed site or a permanent mobile facility.
- b. <u>Sub-facility</u> is physically separate from, but considered an extension of, its main facility. Although it may have all staff, equipment, procedures, and documentation necessary to perform the requisite tests, it receives technical direction and quality assurance management from the <u>main facility</u>.
  - A <u>permanent sub-facility</u> maintains staff, equipment, procedures, documentation, and facilities necessary to perform the tests, for which it seeks accreditation, at all times. It may be a permanently fixed site or a permanent mobile facility and is expected to remain in operation for at least one year.
  - 2. A <u>temporary sub-facility</u> is provided with staff, equipment, procedures, documentation, and facilities necessary to perform the tests, for which it seeks accreditation, on an interim basis, to meet the needs of the <u>main facility</u>. A <u>temporary sub-facility</u> may be established at a fixed site or in a mobile facility and is expected to remain in operation less than one year.

# Conditions for Accreditation:

NVLAP accreditation of a laboratory <u>main facility</u> does not extend to accreditation of <u>sub-facilities</u> unless the <u>sub-facilities</u> have been separately evaluated. These facilities are uniquely identified in the NVLAP accreditation documents. A NVLAP-accredited laboratory must not present or report test data, produced at any non-accredited, <u>sub-facility</u> as having been produced under the status of NVLAP accreditation.

NVLAP offers accreditation to laboratories that are found competent to perform specific test methods or types of tests in specified fields of testing. Competence is defined as the ability to meet specific technical criteria relating to quality assurance, staff, equipment, facilities, procedures, records, and reports. Technical criteria may or may not be equally applicable

to <u>main facilities</u> and <u>sub-facilities</u>. Accreditation of <u>sub-facilities</u> may require NVLAP criteria that address the use and maintenance of equipment and facilities, and the implementation of procedures, that are particularly applicable to the performance of specific test methods in <u>sub-facilities</u>. NVLAP must develop specific technical criteria upon which to base an objective evaluation of staff, facilities, equipment, and procedures employed in applicable <u>sub-facilities</u>.

NVLAP will accredit a <u>main facility</u> if the facility complies with all applicable NVLAP criteria.

NVLAP will accredit a sub-facility (in addition to the main facility) if:

- a. the laboratory main facility meets all NVLAP accreditation criteria;
- b. the laboratory <u>main facility</u> satisfactorily documents and maintains quality assurance procedures addressing the applicable <u>sub-facility</u>; and,
  - c. the <u>sub-facility</u> complies with all applicable NVLAP criteria.

## Procedures:

In principle, NVLAP will require that <u>sub-facilities</u>, to be included in a laboratory's accreditation, undergo on-site assessments and participate in proficiency testing. NVLAP staff, with the guidance of NVLAP technical experts, will determine the need for and extent of such evaluations based on the number and location of similar <u>sub-facilities</u> managed by the laboratory, the nature of the quality assurance system, and any special technical considerations. Decisions on the need for and extent of the evaluations may not be made until after the accreditation of the <u>main facility</u>. The conditions and requirements for evaluation of sub-facilities providing specific testing services are described in NVLAP documents pertaining to the relevant accreditation program.

Laboratories seeking NVLAP accreditation should clearly state, on the NVLAP Application Form, what type(s) of <u>sub-facilities</u> are to be included in the accreditation. NVLAP fees for on-site assessments and proficiency testing will be based on the number of facilities seeking accreditation that are required to undergo on-sites and participate in proficiency testing. A single administrative/technical support fee is charged to the laboratory (<u>main facility</u>).

#### APPENDIX E

#### GENERAL OPERATIONS CHECKLIST

**Instructions to the Assessor:** This checklist addresses general accreditation criteria prescribed in Section 7.33, Subpart D, of the NVIAP Procedures (Title 15 of the Code of Federal Regulations).

Place an "X" beside any of the following items which represent a deficiency. Place a "C" beside each item which you are commenting on for other reasons. Record the item number and your written deficiency explanations and/or comments on the appropriate comment form(s). Place a check beside all other items you observed or verified at the laboratory.

	Quality System.				
1.	The laboratory operates under an internal quality assurance program appropriate to the type, range, and volume of work performed.				
2.	. The quality assurance program is documented in a quality manual or equivalent (e.g., operations notebook) available for use by laboratory staff.				
3.	A person(s) is identified as having responsibility for maintaining the quality manual.				
	The quality manual includes, as appropriate:				
4.	quality assurance responsibilities for each staff position in the laboratory;				
5.	specific quality assurance practices and procedures for each test or type of test, such as control charts, use of reference materials, and inter-laboratory tests;				
6.	procedures for document control, sample control, data validation, corrective action for detected test discrepancies;				
7.	procedures for dealing with testing complaints from clients.				
8.	The laboratory periodically reviews its quality assurance system to ensure the system's continued effectiveness and records the review and any specific corrective actions taken to resolve testing deficiencies.				
	<u>Staff</u>				
<u> </u>	The laboratory has a job description for each position, including any required education, training, technical knowledge, and experience.				
10.	The laboratory documents the test methods each staff member has been assigned to perform.				
11.	The laboratory has a written description of its training program.				
12.	Staff members are not subjected to undue pressure or inducement that might influence their judgement or the results of their work.				
13.	Staff members are aware of both the extent and limitation of their area of responsibility.				
14.	The laboratory has a technical manager (or similar title) with overall responsibility for the technical operations of the laboratory.				
	Facilities and Equipment				
15.	The laboratory has all necessary items of equipment and facilities for the correct performance of the tests and measurements for which accreditation is being sought.				
16.	All equipment is properly maintained.				
17.	Instructions for proper equipment maintenance are available.				
18.	Equipment which has been overloaded or mishandled, gives suspect results, or is defective, is taken out of service until repaired.				

19. When placed back in service, repaired equipment is shown to be performing satisfactorily.

20. Records of each major item of equipment are maintained including: a. name of the item of equipment;				
b. manufacturer's name; c. type, identification, and serial number;				
d. date received and date placed in service;				
e. current location, where appropriate; f. details of maintenance;				
g. date of last calibration, next calibration due date, and calibration report references.				
<u>Calibration</u> The laboratory:				
21. calibrates new or repaired testing equipment before putting it into service;				
22. calibrates, at regular intervals, in-service testing equipment with the calibration status readily available to the operator;				
23. performs checks of in-service testing equipment between the regular calibration intervals, where relevant;				
24. maintains adequate records of all calibrations;				
25. provides traceability of all calibrations and reference standards of measurement where these standards exist or satisfactory evidence of the accuracy or reliability of test results.				
Test Methods and Procedures The laboratory:				
26. performs the test methods and procedures for which accreditation is being sought.				
27. explains departures from standard test methods to clients and records departures in the test report;				
28. has data to prove that departures from standard methods do not detract from the expected or required precision of the measurement;				
29. keeps instructions, testing standards, specifications, manuals, and reference data up-to-date and readily available to the staff;				
30. maintains a system for identifying samples or items to be tested;				
31. maintains procedures for receipt, retention, and disposal of test items.				
Records The laboratory:				
32. maintains a record system with sufficient information to permit report verification;				
33. retains original observations, calculations and derived data, and calibration records for one year unless a longer period is specified;				
34. holds records secure and confidential.				
Test Reports				
35. The laboratory issues accurate, clear test reports.				
Test reports include, as applicable, the:				
36. name and address of the laboratory or other appropriate, unique identification;				
37. identification of the test report by serial number, date, or other appropriate means;				
38. name and address of client or other appropriate unique identification;				
39. description and identification of the test specimen, sample, or lot of material represented;				
40. identification of the test specification, method, or procedure used;				
41. description of sampling procedure, if appropriate;				

42	. deviations, additions to, or exclusions from the test specifications;
43	. measurements, examinations, and derived results supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified;
44	. a statement of measurement uncertainty, where relevant;
45	. a statement that the report must not be used by the client to claim product endorsement by NVIAP or any agency of the U. S. Government;
46	. a statement to the effect that the test report relates only to the items tested.
47	. All test reports endorsed with the NVLAP logo contain the signature of an approved signatory.



## APPENDIX F

#### SPECIFIC OPERATIONS CHECKLIST

## BULK ASBESTOS LABORATORY ACCREDITATION PROGRAM

Instructions for the Assessor: This checklist addresses specific accreditation criteria prescribed in Section IV. <u>TECHNICAL REQUIREMENTS</u> of the Bulk Asbestos Analysis Handbook. These criteria <u>do not</u> supercede the <u>Criteria for accreditation</u>, based on Section 7.33 of the NVLAP Procedures, which are addressed in the GENERAL OPERATIONS CHECKLIST.

Place an "X" beside any of the following items which represent a deficiency. Place a "C" beside each item which you are commenting on for other reasons. Record the item number and your deficiency explanation and/or comments on the appropriate comment form(s). Place a check beside all other items you observed or verified at the laboratory.

# QUALITY SYSTEM

1. The laboratory's Quality Assurance (QA) analyses represent at least 10% of the total number of analyses performed
2. Results of the QA analyses are summarized at least monthly and include
<ul> <li>a. results from blanks</li> <li>b. results from duplicate, replicate analyses</li> <li>c. results from internal and NIST proficiency testing for each operator</li> <li>d. results from inter-laboratory analyses</li> <li>e. deficiency corrections</li> <li>f. overall accuracy, precision for each microscopist</li> </ul>
3. The laboratory's Quality Manual contains or refers to procedures covering:
<ul> <li>a. log-in of sample materials</li> <li>b. criteria for acceptance or rejection of materials for test</li> <li>c. sample custody</li> <li>d. description of materials</li> <li>e. sample preparation</li> <li>f. sample analysis</li> <li>g. contamination testing including frequency and timing of checks for contamination of laboratory equipment or supplies including glass slides, coverslips, refractive index liquids, sampling instruments, analytical instruments (microscopes), work stations, cleaning fluids</li> <li>h. contamination control; maintenance of a contamination-free work space</li> <li>i. instrument and materials calibration</li> <li>j. staff qualifications</li> <li>k. laboratory characterization</li> </ul>
4. The Quality Manual describes how routine checks of analysts' competence are performed using:
<ul><li>a. duplicate and replicate analyses</li><li>b. internal and NIST proficiency testing</li><li>c. comparison with other operators (including one outside the laboratory)</li></ul>
5. The Quality Manual describes staff training programs
6. The Quality Manual describes how accuracy and consistency of analyses are assured.
7. The Quality Manual specifies frequency and timing of equipment calibration and verification of refractive index liquids.
8. The Quality Manual describes the laboratory's record-keeping system.

9. A quality assurance supervisor is designated to define and maintain the Quality System and

the associated Quality Manual.

10.	The following documents are available in the laboratory as reference:
a. b.	General reference text on optical mineralogy or crystallography 40 CFR Part 763, Vol. 52, No. 210 "Asbestos-Containing Materials in Schools; Final Rule and Notice"
c.	Draft ASIM method for Polarized Light Microscope Analysis of Asbestos Containing Material.
STAFF	
	Analysts and supervisors are qualified to conduct polarized light microscopy and its application to crystalline materials including the measurement of the index of refraction by the immersion method through Becke line technique and/or dispersion staining.
12.	The laboratory maintains a personnel folder for each staff member including:
b. c. d. e. f.	position description/job responsibilities resume of qualifications training assigned laboratory procedures results of periodic quality assurance testing reviews including intra-operator tests, inter-operator tests and between-laboratory tests accuracy and precision summary data correction of deficiencies
FACILITI	ES AND EQUIPMENT
13.	The laboratory properly stores bulk asbestos
14.	Safe working conditions while handling bulk asbestos are maintained.
15.	The laboratory has the following materials and equipment in working order:
b. c. <b>d</b> . e.	to 0.005 (high dispersion liquids are optional) magnifying glass or low power binocular microscope, approximately 10-45x, with light source mortar and pestle
16.	The laboratory has polarized light microscope(s) with:
b. c. d. e. f.	360 degree rotatable stage substage condenser with iris diaphragm polarizer and analyzer which can be placed at 90 degrees to one another accessory slot for wave plates and compensators wave retardation plate: approximately 550 nanometer
CALIBRAT	<u>TION</u>
17.	The laboratory keeps records detailing calibration and maintenance.
18.	The polarized light microscope is calibrated as follows:
	The substage polarizer and the analyzer are oriented at 90 degrees to one another. (The requirements are that the orientations are known, that they are normal to one another, and that the accessory slot be 45° to the privileged directions of the polarizer and analyzer.)
b.	The ocular crosshairs coincide with the privileged directions of the polarizer and the analyzer.
c. d.	stage rotation.
u.	The substage conneitset and title ordentable are concern in the opera with

19.	Refractive index liquids are calibrated with an accuracy of .004. Calibration procedure includes temperature accuracy of $2^{\circ}\text{C}$ .		
TEST ME	THODS AND PROCEDURES		
20.	The laboratory uses currently required method for the determination of asbestos in bulk insulation samples.		
21.	Laboratory blanks, using asbestos-free materials are prepared and analyzed with sufficient frequency to detect contamination. $ \frac{1}{2} \int_{-\infty}^{\infty} \frac{1}{2} \left( \frac{1}{2} \int_{-\infty}^{\infty} \frac{1}{2} $		
22.	The laboratory has written procedures covering all aspects of asbestos:		
b	. handling . analysis . storage . disposal		
23.	Procedures are readily accessible to all applicable personnel.		
RECORDS			
24.	Records are kept of all quality assurance activities.		
25.	Records are readily accessible and adequate security is maintained to assure long-term survival of records.		
26.	Sample log includes:		
b	date of receipt condition date of receipt condition		
27.	Analyst(s) determine and record the following optical properties:		
a b	or bulk examination  homogeneity  texture  color  estimated amount of asbestos		
e f g fi i j k	or PIM examination . morphology . color and pleochroism . index of refraction parallel and perpendicular to elongation . birefringence . extinction characteristics . sign of elongation . other distinguishing characteristics . estimated amount of asbestos . results of analysis (see TEST REPORT)		
28.	The analyst signs or initials and dates each analysis recorded in the laboratory note book.		
29.	Equipment records include information on:		
b c d e	manufacturer model serial number major components calibration maintenance/service location of manuals		

IEST REPORTS			
30.	The following is reported for each sample:		
b. c. d. e.	color presence or absence of asbestos type or types of asbestos present estimate of the relative abundance of each type of asbestos present estimate of the relative abundance of other fibrous materials present identity of other fibrous materials and matrix materials		
31.	A statement is made if the sample is inhomogeneous and subsamples of the components were analyzed separately		
32.	Separate components (e.g. layers) are reported separately and are combined in proportion to their abundances and a single analysis is provided for the sample.		
PROFICI	ENCY TESTING		
33.	Analyses not contracted out to another laboratory.		
34.	Laboratory keeps proficiency testing materials for use as in-house instructional materials.		
35.	All analysts participate in proficiency testing.		
36.	Each analyst separately analyzes, records, and reports test results.		
37.	One single result is reported back to NVIAP by the laboratory.		
38.	The test results are used for inter-analyst comparisons.		

\_39. Problems indicated by proficiency testing are discussed with appropriate laboratory personnel

40. Plans are developed and implemented for resolving problems.

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